EXTERNAL BREAST PROSTHESIS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 12/915,365 filed on Oct. 29, 2010 which claims the benefit of U.S. Provisional Application No. 61/255,910, filed on Oct. 29, 2009. The entire disclosure of the above applications are incorporated herein by reference.

FIELD

The present disclosure relates to a breast prosthesis and method of fabricating same, and in particular to an external air-filled breast prosthesis having a human-like appearance.

BACKGROUND

This section provides background information related to the present disclosure which is not necessarily prior art.

The use of prosthesis is well known for the purpose of replicating or augmenting anatomical features of the human body, and in particular the human breast. To be acceptable, a breast prosthesis must accurately replicate the size and shape of the anatomy, as well as the function of such anatomy. In addition, the prosthesis must be ergonomically compatible and comfortable for the wearer.

The art is replete with various internal and external breast prostheses. In some instances, a relatively thin outer elastic shell is formed from an elastic silicone material. In these embodiments, the prosthesis is either made of solid silicon or the interior cavity of the prosthesis is filled with a material which provides internal support. Such filler materials may include various foams or other biocompatible fluids such as saline, silicone gel or natural triglyceride oils. These prostheses have a tendency to be heavy and/or inaccurate at replicating the form and function of the subject anatomy.

Accordingly, there is a need the art to provide an external breast prosthesis with a thin outer shell formed of an elastomeric material and an interior air-filled cavity, as well as a method and die set for fabricating such an external breast prosthesis.

SUMMARY

This section provides a general summary of the disclosure, and is not a comprehensive disclosure of its full scope or all of its features.

As further set forth in detail below, this disclosure provides an external breast prosthesis having a thin-walled outer shell and an air-filled internal cavity. The prosthesis is fabricated using a process and die set which provides a two part shell including an anterior cup-shaped portion and a posterior backer which when assembled defines an air-tight cavity. The nipple structure of the prosthesis is formed with a rayon flocking material having a fleshy color consisting of various tints of red, purple and gold. The outer shell is formed of an elastomeric material, preferably an elastic silicone material which has been vacuum treated to remove air that would otherwise cause bubbles, pits or voids in the thin-walled prosthesis. This disclosure further provides a method and die set for fabricating the thin-walled air-filled prosthesis.

Further areas of applicability will become apparent from the description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

DRAWINGS

The drawings described herein are for illustrative purposes only of selected embodiments and not all possible implementations, and are not intended to limit the scope of the present disclosure.

FIG. **1** illustrates a first mold assembly in which the anterior cup-shaped portion of the prosthesis is formed;

FIG. **2**A illustrates a second molding assembly in a pre-assembled state with a thickened layer of elastic silicone material spread on the die plate;

FIG. **2**B illustrates the second molding assembly shown in FIG. **2**A with the die cavity placed on top of the die plate;

FIG. **3** is an illustration of the breast prosthesis in its finalized form; and

FIG. **4** is a flow chart setting forth the processing steps used in the fabrication of the breast prosthesis.

Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION

Example embodiments will now be described more fully with reference to the accompanying drawings.

With reference now to the figures, an external breast prosthesis **10** having a thin-walled elastomeric shell **12**, **16** with an air-filled interior cavity **18** is illustrated. In addition, the method and die set for fabricating this prosthesis is illustrated and described. With particular reference to FIGS. **1**-**3**, the external breast prosthesis **10** includes a thin-walled anterior shell **12** having a perimeter edge portion **14** joined to a thin-walled posterior shell **16**. In this configuration the anterior shell **12** and posterior shell **16** are arranged to define an air-filled interior cavity **18**. The anterior shell **12** has a nipple/areola region **20** formed therein. As best seen in FIG. **3**, the perimeter edge **14** of the anterior shell **12** is a chamfered perimeter edge **14** formed thereon which complements the edge defined by the posterior shell **16**. In particular, the perimeter edge **14** bisects the interface between anterior shell **12** and posterior shell **16** to form a mitered joint. As noted above, the prosthesis is fabricated with an elastomeric material, preferably an elastic silicone material.

The breast prosthesis **10** is fabricated by injection molding the anterior shell **12** and then position forming the posterior shell **16** onto the anterior shell. The die sets **30**, **50** used in this fabrication process sufficiently support the anterior shell **12** such that the prosthesis can be fabricated with an air-filled cavity and without internal support. In particular, a first mold assembly **30** as shown in FIG. **1** includes a lower die **32** and an upper cover **34**. A series of pins **36** extend across the die separation surface and align the upper cover **34** with the lower die **32**. The lower die **32** has a generally concave die cavity **38** formed therein. The bottom region **40** of the die cavity **38** is shaped to replicate the nipple/areola region of a human breast.

As presently preferred, the die cavity **38** is formed using a machining process which yields a Class-A exterior surface for the anterior shell **12** of the breast prosthesis **10**. In particular, the interior die cavity **38** is machined to a precision surface based upon **3**-dimensional modeling data similar to the techniques utilized in fabrication of automotive body panels. The upper die cover **34** has a generally convex surface **42** which complements the concave surface **38** formed on lower die **32**. The convex surface **42** terminates at an angled